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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,377	02/07/2002	Timothy B. Karpishin	269/003	1762

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,377

Applicant(s)

KARPISHIN ET AL.

Examiner

Brenda Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 8-10, 12-25, 33-35, 39-41 and 46-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11, 26-32, 36-38 and 42-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/4/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-49 are pending in the application.

Election/Restrictions

1. Applicant's election with traverse of Group IV in the reply filed on April 22, 2004 is acknowledged. The traversal is on the ground(s) that the claims as grouped are from the same inventive effort and project. This is not found persuasive because the compositions of the instant invention embrace a wide variety of amphiphilic modules, i.e. macrocyclic ring structures.

Note MPEP 2173.05(h) "where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by a consideration of the compound as a whole, and does not depend on there being a community of properties in the members of the Markush expression. Therefore, what should be considered for patentable distinctness is the compound as a whole. Would a whole compound where the compound is a hexamer compound be patentably distinct from a whole compound where the compound is a tetramer or octamer? If a reference for one would not be a reference for the other, then restriction is considered proper. It is the compound as a whole a hexamer of formula 1jh vs. a tetramer of example 64 vs. an octamer of formula 5jh or 4jh, etc., that must be considered for patentable distinctness.

Thus, separate searches in the literature would be required. However, should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either

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instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 8-10, 12-25, 33-35, 39-41 and 46-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 22, 2004.

3. A search of the applicants elected species was done as well as amphiphilic modules which comprise three 1,3-phenylene rings and three 1,2-cyclohexane rings or 1,3-cyclohexane rings linked together by -C~N- where the nitrogen atom is bonded to the cyclohexane rings.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7, 11, 26-32, 36-38 and 42-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

HOW TO MAKE: In evaluating the enablement question, several factors are to be considered. In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988), Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. The nature of the invention in the instant application, has claims which embrace amphiphilic module compositions with from three to about twenty-four cyclic synthons coupled to form a closed ring. The cyclic synthons are not described in the disclosure in such a way the one of ordinary skill in the art would know how to prepare the various compositions suggested by claims 1-7, 11, 26-32, 36-38 and 42-45. Examples spanning pages 64-66 describe compounds which form tetramers and hexamers which possess only phenylene and cyclohexane rings. There is no teaching in the specification of how to make the magnitude of possible

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compounds claimed herein. For example where are the starting materials for the preparation of compounds where the amphiphilic module is made up of pyridine rings, bicycle[2.2.1]heptene rings, 1,3-diazabicyclo[2.2.1]heptane rings, etc. and various combinations thereof. In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples, and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to make the claimed compositions and therefore practice the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 4, 5 and 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 4 is vague and indefinite in that it is not known what is meant by the definition of the hydrophilic moiety where the moieties are $-^+NRR'R''$, $-SO_3^-$, $-OPO_2^{2-}$, $-C(O)O^-$. There is no indication of the counter ion needed to charge balance the compound when these moieties are present.
- b) Claim 5 is vague and indefinite in that it is not known what is meant by the variable m , which is not defined within the claim.
- c) Claim 5 is vague and indefinite in that it is not known what is meant by the moiety $-C(OH)CH(NHR^{17})-$, where the C only has three bonds.

- d) Claim 5 is vague and indefinite in that it is not known what is meant by the moiety C(O)NR^{17} -, which is missing the second point of attachment.
- e) Claim 5 is vague and indefinite in that it is not known what is meant by the moiety $-\text{CH(OH)CH}_2(\text{CO}_2\text{R}^{17})$ -, where the C has five bonds.
- f) Claim 5 is vague and indefinite in that it is not known what is meant by the moiety $-\text{C}(\text{CHR}^{17}\text{R}^{18})\text{S}$ -, where the C only has three bonds.
- g) Claim 5 is vague and indefinite in that it is not known what is meant by the moiety $-\text{C(O)CH}_2(\text{CO}_2\text{R}^{17})$ -, where the C has five bonds.
- h) Claim 5 is vague and indefinite in that it is not known what is meant by “a group that confers a selected chemical or physical characteristic”.
- i) Claim 26 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the definition of R_2 , R_4 , R_6 , R_8 , R_{10} and R_{12} which begins with a capital letter, i.e. One.
- j) Claim 26 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the definition of R, where R is “a group that confers a selected chemical or physical characteristic”.
- k) Claim 26 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the definition of A and L, where A and L is “substituents that confers a selected chemical or physical characteristic”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4-7, 11, 26-31 and 42-45 are rejected under 35 U.S.C. 102(b) as being anticipated by KORUPOJU et al., Chemical Communications. KORUPOJU teaches the compounds of the instant invention where the macrocyclic module consists of three 1,2-cyclohexane synthons and three 2-hydroxy-5-methyl-1,3-phenylene synthons coupled together by -N=CH- or -NH-CH₂- functional groups. See examples 1 and 2 on page 1267.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-7, 11, 26-32, 36-38 and 42-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of copending Application No. 10/226,400. Although the conflicting claims are not identical, they are not patentably distinct from each other because the macrocyclic module compositions of the instant invention are embraced by the

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amphiphilic modules of U.S. Application No. 10/226,400, such as the elected species of the instant invention where the macrocyclic module consists of three 1,2 cyclohexane rings and three 1,3-phenylene rings as shown by the claim 30.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Brenda Coleman
Primary Examiner Art Unit 1624
July 2, 2004